JUN 22 2000

Marconi 510(k) Notice
#K001088

UltraSIM

SUBSTANTIAL EQUIVALENCE SUMMARY

The following information is being supplied in accordance with 21CFR 807.92(a) and in the order specified in that section.

(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

Submitter: Marconi Medical Systems, Inc.
595 Miner Road
Cleveland, OH 44143
(440) 483-3000

Contact: Robert L. Turocy
Marconi Medical Systems
595 Miner Road
Cleveland, OH 44143
(440) 483-3528

Date of Summary: May 17, 2000

(2) The name of the device, including the trade name or proprietary name if applicable, the common name or usual name, and the classification name, if known:

Device Name
(Proprietary Name): UltraSIM

Classification Name: Computed Tomography X-Ray System

Common Name: Computed Tomography X-Ray System

The FDA has classified the UltraSIM as Class II in 21 CFR 892.1750
(Product Code 90JAK)

K001088 Page 2 of 3

Continued ULTRASIM SUBSTANTIAL EQUIVALENCE SUMMARY

(3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared to for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from Class III to Class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) Premarket Notification process.

In the opinion of Marconi Medical Systems Inc., the UltraSIM is of comparable type and substantially equivalent to the legally marketed devices currently in commercial distribution, namely the PQ2000+, now identified as Ultra-Z, in CDRH Document Control No K955268. See Attachment "E", Comparison Matrix.

This opinion is based on the fact that comparing the PQ2000+, now identified as Ultra-Z, with the UltraSIM reveals that both devices comply with the same or equivalent standards and have the same or equivalent intended uses.

(4) A description of the device that is the subject of the Premarket Notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device such as device design, material used, and physical properties.

The UltraSIM is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

Functional specifications and operator's instructions (preliminary) are included in the attachments.

The UltraSIM is substantially equivalent to legally marketed devices. The UltraSIM is under the control of health care professionals who are trained and responsible for computed tomography examinations. The UltraSIM will be certified to comply with Federal Diagnostic X-Ray Performance Standards. Labeling (Product Specification and Operator's Manual) will be provided to the user of the equipment.

Marconi Medical Systems, Inc. adheres to FDA GMPs, 21 CFR 1020.30-33, and voluntary standards for safety/effectiveness (UL 2601) all of which mandate that components are tested to minimize hazards (electrical, mechanical, and radiation).

K001033
page 3 of 3

Continued ULTRASIM SUBSTANTIAL EQUIVALENCE SUMMARY

(5) A statement of the intended use of the device that is subject of the Premarket Notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or will mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled;

The UltraSIM is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This device may include signal analysis and display equipment, patient, and equipment supports, components and accessories.

(6) If the device has the same technological characteristics (i.e., design material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.

The UltraSIM is of comparable type and substantially equivalent to the legally marketed devices currently in commercial distribution, namely the PQ2000+, now identified as Ultra-Z, in CDRH Document Control No K955268. See Attachment "E", Comparison Matrix.

This opinion is based on the fact that comparing the PQ2000+ (now identified as Ultra-Z) to the UltraSIM reveals that both devices comply with the same or equivalent standards and have the same or equivalent intended uses.

Both the UltraSIM and the PQ2000+ are Computed Tomography X-Ray Systems intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2000

Robert L. Turocy
Regulatory Affairs & Compliance Manager
Marconi Medical Systems, Inc.
595 Miner Road
Highland Heights, OH 44143

Re: K001088
UltraSIM CT System
Dated: March 17, 2000
Received: April 4, 2000
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Turocy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(K) Number (if known): **K001088**

Device Name: UltraSIM CT System

INDICATIONS FOR USE:

The UltraSIM is a Computed Tomography X-Ray System intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001088

Prescription Use X
(Per 21 CFR 801.109

OR

Over-the –Counter Use_____